



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,192	12/22/2003	Peter M. Bonutti	2500DV2CN2DV3CN7	6862

7590 01/16/2009
Kimberly V. Perry, Esq.
U.S. Surgical
A Division of Tyco Healthcare Group, LP
150 Glover Avenue
Norwalk, CT 06856

EXAMINER

MANAHAN, TODD E

ART UNIT	PAPER NUMBER
----------	--------------

3731

MAIL DATE	DELIVERY MODE
-----------	---------------

01/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte PETER M. BONUTTI

Appeal 2008-5877
Application 10/743,192
Technology Center 3700

Decided: January 16, 2009

Before TONI R. SCHEINER, DEMETRA J. MILLS and
LORA M. GREEN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1-4 and 7. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to a fluid retractor. Claim 1 is representative of the claims on appeal, and reads as follows:

1. An apparatus comprising:
a rigid shaft having an open first end and an open second end defining a lumen therebetween; and
an inflatable bladder disposed at the distal end and in fluid communication with the lumen, the inflatable bladder having the shape of a wedge upon inflation such that the inflatable bladder separates adjacent portions of bone tissue thereby creating a working space.

The Examiner relies on the following reference:

Sheldon	US 3,417,745	Dec. 24, 1968
---------	--------------	---------------

We affirm.

ISSUE

The Examiner concludes that claims 1-4 and 7 are anticipated under 35 U.S.C. § 102(b), or in the alternative, obvious under 35 U.S.C. § 103(a), over Sheldon.

Appellant contends that Sheldon does not disclose or suggest a shaft having open first and second ends defining a lumen therebetween with an inflatable bladder disposed at the distal end of the shaft.

Thus, the issue on Appeal is: Has Appellant demonstrated that the Examiner erred in concluding that Sheldon discloses or suggests a shaft

having open first and second ends defining a lumen therebetween with an inflatable bladder disposed at the distal end of the shaft?

FINDINGS OF FACT

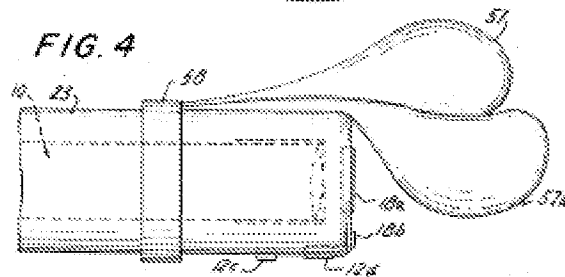
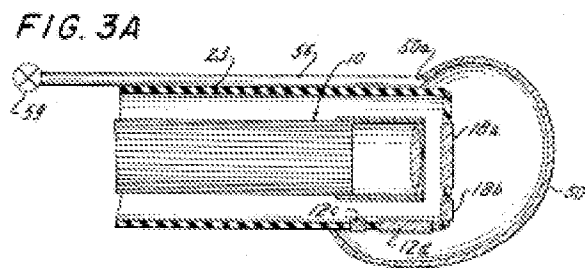
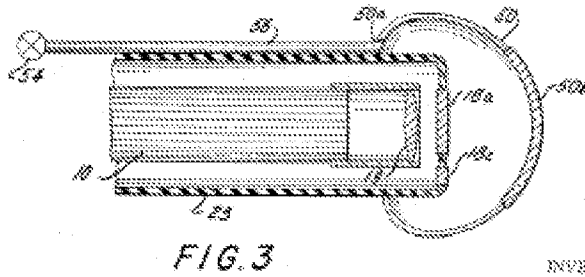
FF1 The “present invention relates to fluid operated apparatus for use in moving apart abutting tissues, during surgery, in order to create[] a space between the tissues to improve visualization and for increased working space during open surgery and fiberoptic assisted surgery.” (Spec. 1.)

FF2 The retractor includes a fluid operated portion, such as a bladder or balloon, which is used to retract the tissue (*id.* at 3). The bladder is made of materials “such as Kevlar or Mylar which may be reinforced with stainless steel, nylon, or other fiber to prevent puncturing and to provide structural shape and support as desired.” (*Id.* at 4.)

FF3 The Examiner rejects claims 1-4 and 7 under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a), as being obvious over Sheldon (Ans.¹ 3). As Appellant does not argue claims 2-4 separately from claim 1, those claims stand or fall with claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

¹ All references to the Answer are to the Examiner’s Answer dated March 27, 2006.

FF4 The Examiner relies on Figures 3 and 4 of Sheldon, reproduced below.



Figures 3, 3A, and 4 show a spinescope according to Sheldon, on which an inflatable member is provided (Sheldon, col. 2, ll. 28-31).

FF5 As shown in Figure 3, the inflatable member has an opening 50 connected to channel 56 (i.e., in fluid communication with the shaft 56) that is attached to a fluid or gas source (*id.* at col. 8, ll. 62-68).

FF6 Although not shown, the Examiner asserts that Sheldon discloses a shaft for inflating the bladder 57 or 57a (element 56 in Figure 3), that is rigid or reinforced by attachment to the spinescope (Ans. 3).

FF7 The Examiner further finds that bladders 57 and 57a have the shape of a wedge upon inflation as they taper in the proximal direction, and that the bladders would be able to separate adjacent portions of bone tissue, as they may be constructed from mylar, which is one of the materials used by Appellant (*id.* at 4-5).

FF8 As to claim 7, the Examiner finds that Sheldon discloses a needle having a passage that receives the spinescope (*id.* at 7). The Examiner finds further that Sheldon teaches that the tip of the needle does not have a closing wall.

FF9 Moreover, Sheldon teaches that the use of an inflatable means applies to all of the embodiments described in the patent (Sheldon, col. 9, ll. 24-25).

PRINCIPLES OF LAW

Our mandate is to give claims their broadest reasonable interpretation. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). “An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.” *In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989).

As to anticipation, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the

claim. *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001).

As to obviousness, the question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court has recently emphasized that “the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at 1739. Moreover, an “[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious.” *In re Fout*, 675 F.2d 297, 301 (CCPA 1982).

ANALYSIS

Appellant argues that “Sheldon does not anticipate or render obvious any of the claims on appeal because Sheldon fails to disclose or suggest a

shaft having open first and second ends defining a lumen therebetween with an inflatable bladder disposed at the distal end of the shaft.” (App. Br.² 4.)

According to Appellant, Sheldon “discloses a device having a hollow tube with a closed distal end wherein at least one window is included in the closed distal end,” wherein the inflatable member is attached along the exterior of the device such that the windows are not encased (*id.* at 4-5). Thus, Appellant asserts, “a separate inflation tube extends along the exterior of Sheldon’s device and is fluidly coupled to the inflatable member.” (*Id.* at 5.) Appellant therefore argues that Sheldon, “[r]ather than disclosing or suggesting a shaft having an open first end and an open second end, . . . specifically discloses a device wherein one end of the device is closed and the inflatable member is attached along the exterior of the device.” (*Id.* at 6.)

Claim 1 recites an “apparatus comprising 1) a rigid shaft having an open first end and an open second end defining a lumen therebetween; and 2) an inflatable bladder disposed at the distal end and in fluid communication with the lumen, the inflatable bladder having the shape of a wedge upon inflation such that the inflatable bladder separates adjacent portions of bone tissue thereby creating a working space.” The use of the open transition phrase “comprising” allows for the addition of other components. In addition, the recitation that “the inflatable bladder separates

² All references to the Appeal Brief (App. Br.) are to the Appeal Brief dated March 27, 2006.

adjacent portions of bone tissue thereby creating a working space,” is merely a statement of intended use and not a patentable limitation.

Therefore, all that is required by claim 1 is a rigid shaft having a lumen, wherein an inflatable bladder is disposed at one end of the shaft, wherein the bladder is in fluid communication with the lumen of the shaft, wherein the inflatable bladder has a wedge shape upon inflation.

The channel (element 56 in Figure 3, not shown in Figure 4) that is used to inflate the inflatable transparent member of Sheldon (*see* FF5 and 6) reads on the shaft of claim 1. The fact that it may be on the outside or on the inside of the spinescope of Sheldon is irrelevant, as all that is required by the claim is a rigid shaft having a lumen, wherein an inflatable bladder is disposed at one end of the shaft, wherein the bladder is in fluid communication with the lumen of the shaft. In addition, as both Sheldon and the instant Specification teach the use of inflatable bladders made from mylar, the mylar bladder of Sheldon would be capable of performing the intended use of separating adjacent portions of bone tissue.

Thus we find that Sheldon anticipates the subject matter of claim 1. In the alternative, as the shaft is not specifically shown in Figure 4, we conclude that it would have been *prima facie* obvious to the ordinary artisan to attach a rigid shaft to the bladder of the spinescope in Figure 4 so that it may be attached to a gas or fluid source for inflation. The rejection is thus affirmed as to claim 1, and as claims 2-4 stand or fall with that claim, the rejection is affirmed as to those claims as well.

As to claim 7, Appellant argues that claim 7 “recites that the apparatus includes a cannula having a passage that receives the shaft to deploy the bladder at a target site in the tissue.” (App. Br. 6.) Appellant asserts that the spinal needle of Sheldon does not meet the limitation added in claim 7, as Sheldon specifically teaches that the disclosed device is maintained within the spinal needle, whereas the claimed device includes “a cannula having a passage for deploying the bladder at a target site in tissue.” (*Id.* at 7.)

Claim 7 recites the “apparatus as in claim 1, further comprising a cannula having a passage which receives the shaft to deploy the bladder at a target site in the tissue.” As noted by the Examiner, Sheldon teaches a needle for receiving the spinescope (which would include the shaft for inflating the bladder), wherein the tip has no closing wall (FF8). Thus, even though the spinescope (and the shaft) remain in the needle, an inflatable bladder could be deployed through the end of the needle as it contains no closing wall. Thus, although not specifically exemplified, we conclude that the Examiner has established that claim 7 is anticipated by and/or rendered obvious by Sheldon.

CONCLUSIONS OF LAW

We conclude that Appellant has not demonstrated that the Examiner erred in concluding that Sheldon discloses or suggests a shaft having open first and second ends defining a lumen therebetween with an inflatable bladder disposed at the distal end of the shaft, and we thus affirm the rejection of claims 1-4 and 7 under 35 U.S.C. § 102(b) as being anticipated

by, or in the alternative, under 35 U.S.C. § 103(a), as being obvious over Sheldon.

TIME LIMITS

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

dm

KIMBERLY V. PERRY, ESQ
U.S. SURGICAL
A DIVISION OF TYCO HEALTHCARE GROUP
150 GLOVER AVENUE
NORWALK, CT 06856

Appeal 2008-5877
Application 10/743,192